

Article 1. Definitions

(1) Adopt new Section 1029.31 to read:

1029.31. Arterial Puncture.

“Arterial puncture” means the penetration of an artery with a needle to withdraw blood for clinical laboratory test or examination purposes.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.
Reference: Sections 1242, 1242.5, 1242.6, 1243, 1246, and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(2) Adopt new Section 1029.32 to read:

1029.32. Certified Phlebotomy Technician I.

“Certified phlebotomy technician I” means a person who has completed the education, training, experience and examination requirements pursuant to Section 1034 and is certified by the department to perform skin punctures and venipunctures.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1208, 1212, 1242, 1242.5, 1246, and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(3) Adopt new Section 1029.33 to read:

1029.33. Certified Phlebotomy Technician II.

“Certified phlebotomy technician II” means a person who has completed education, training, experience and examination requirements pursuant to Section 1034 and is certified by the department to perform skin punctures, venipunctures and arterial punctures.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.
Reference: Sections 1206, 1208, 1212, 1242, 1242.5, 1246, and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(4) Adopt new Section 1029.34 to read:

1029.34. Certifying Organization.

“Certifying organization”, also called a national accreditation or accrediting board or agency, means an organization, agency or body that creates competency examinations that measure the skill, knowledge and aptitude required of an individual in a profession, occupation or discipline.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1246, 1262, 1264, and 1270, Business and Professions Code; and Section 120580, Health and Safety Code.

(5) Adopt new Section 1029.108 to read:

1029.108. License.

For the purposes of this chapter, "license" means license, certificate, registration or other means to engage in a business or profession regulated by Chapter 3 .

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 23.7, 1203, 1204, 1205, 1206.5, 1207, 1208, 1209, 1209.2, 1210, 1220, 1227, 1242, 1246, 1246.5, 1260, 1260.1, 1261, 1261.5, 1262, 1263, 1264, 1265, 1267, 1269.5, 1270, 1275, 1280, 1281, 1285, 1288.5, 1300, 1301, 1301.1, 1310, 1320, 1322, 1323, 1324, and 1325, Business and Professions Code; and Section 120580, Health and Safety Code.

(6) Adopt new Section 1029.116 to read:

1029.116. Limited Phlebotomy Technician.

“Limited phlebotomy technician” means a person who has completed the education, training and experience requirements pursuant to Section 1034 and is certified by the department to perform skin punctures.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1208, 1212, 1242, 1242.5, 1246, and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(7) Adopt new Section 1029.124 to read:

1029.124. On-the-Job Experience in Phlebotomy.

“On-the-job experience in phlebotomy “ means employment as a phlebotomist in
a clinical laboratory performing the techniques pursuant to Section 1035.1 (f).

NOTE: Authority cited: Section 1224, Business and Professions Code; and
Section 100275, Health and Safety Code.

Reference: Sections 1206, 1242, 1242.5, 1242.6, 1243, 1246, and 1269,
Business and Professions Code; and Section 120580, Health and Safety Code.

(8) Adopt new Section 1029.132 to read:

1029.132. Phlebotomist.

“Phlebotomist” means a person who collects blood for clinical laboratory test or examination purposes.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.
Reference: Sections 1206, 1208, 1212, 1242, 1242.5, 1246, and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(9) Adopt new Section 1029.133 to read:

1029.133. Phlebotomy.

“Phlebotomy” means the process of collecting blood by venipuncture, arterial puncture or skin puncture for the purpose of obtaining blood for clinical laboratory test or examination purposes.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.
Reference: Sections 1206, 1242, 1242.5, 1246, and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(10) Adopt new Section 1029.154 to read:

1029.154. Skin Puncture.

“Skin puncture” means penetration of the skin for the purpose of collecting capillary blood for clinical laboratory test or examination purposes.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.
Reference: Sections 1206, 1242, 1242.5, 1246, and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(11) Adopt new Section 1029.195 to read:

1029.195. Venipuncture.

“Venipuncture” means the penetration of a vein with a needle to withdraw
blood for clinical laboratory test or examination purposes.

NOTE: Authority cited: Section 1224, Business and Professions Code; and
Section 100275, Health and Safety Code.
Reference: Sections 1206, 1242, 1242.5, 1246, and 1269, Business and
Professions Code; and Section 120580, Health and Safety Code.

(12) Amend Section 1031.4 to read:

1031.4. Requirements and Timeframes for Applications for Licensure and
Certification.

~~(b)~~(a) Applications for admission to a state-administered licensing examination shall be complete when the information specified in Section 1031.4~~(a)~~ (b) has been received by the department. For an applicant to be eligible for a scheduled examination, the completed application must be ~~received~~ postmarked at least 120 days prior to the examination date as published by the Department of Health Services, as verified by postmark date of the completed application. When applying for admission to the examination, the applicant shall state whether he or she has previously applied to the department for admission to an examination.

~~(a)~~(b) An application for licensure to direct a clinical laboratory or to perform clinical laboratory tests or examinations under ~~e~~Chapter 3 of the Business and Professions Code shall be considered complete when the following is provided to the department:

(1) Name and address of the applicant, including city, state and zip code; and
(2) Social security number of the applicant (Pursuant to the authority found in ~~s~~Section 1224 of the Business and Professions Code and in ~~s~~Section 100275 of the Health and Safety Code, and as required by Section 17520 of the Family Code, ~~providing it is mandatory to provide~~ the social security number is mandatory. The social security number will be used for purposes of identification.); and

(3) Gender and birthdate; and

- (4) License for which the applicant is applying; and
- (5) Whether the applicant has or has not been convicted of any felonies or misdemeanors other than minor traffic violations; and
- (6) Documentation of the applicant's education including:
 - (A) Name, address, major course of study, dates of attendance, number of credits, and degree/completion date for all colleges and universities attended by the applicant; and
 - (B) Official transcripts from the registrar of all accredited colleges or universities attended by the applicant showing all courses, course credits, degrees conferred and date of conference; and
 - (C) Official transcripts from non-United States colleges or universities which are not in English shall be returned to the applicant to obtain translation from a translation service approved in the United States for legal or government documents.
- (7) Documentation of the applicant's training including:
 - (A) Name and address of training program, dates of training, specialty and subspecialty areas of training, length of time in each specialty and subspecialty area of training; and
 - (B) Signed documentation from the training program director that this training ~~had~~ has been successfully completed; and
- (8) Documentation of the applicant's experience, appropriate to the specific license for which the applicant is applying, including the following:
 - (A) Facility name, address, dates of employment, number of hours per week employed, the specialties and subspecialties in which clinical laboratory tests or

examinations were performed and a description of clinical laboratory tests,
~~procedures and~~ or examinations performed; and

(B) Signed documentation of such experience from the director of the laboratory;
and

(9) Evidence of satisfactory performance on a licensing examination pursuant to
Section 1029.81; and

(10) Signature of the applicant, telephone number and date of application; and

(11) Payment of license application fee pursuant to Business and Professions
Code Section 1300.

(c) An application for certification in phlebotomy shall be considered complete
when the following is provided to the department:

(1) Name and address of the applicant, including city, state and zip code; and

(2) Social security number of the applicant (Pursuant to the authority found in
Section 1224 of the Business and Professions Code and in Section 100275 of
the Health and Safety Code, and as required by Section 17520 of the Family
Code, it is mandatory to provide the social security number. The social security
number will be used for purposes of identification.); and

(3) Gender and birthdate; and

(4) Category of phlebotomy certification for which the applicant is applying; and

(5) Whether the applicant has or has not been convicted of any felonies or
misdemeanors other than minor traffic violations; and

(6) Documentation of the applicant's education including:

(A) Name, address, dates of attendance, coursework completed and
graduation as verified by official school transcripts; or

(B) Documentation of a passing score on the general educational

development (GED) test or equivalent education as evaluated by the American Association of Collegiate Registrars and Admissions Officers for secondary education; or

(C) For official school transcripts which are not in English, documentation of equivalent education as obtained through translation into English from a translation service approved in the United States for legal or government documents; and

(7) Certification of the applicant's instruction in phlebotomy as specified in Section 1035.1 (h); and

(8) Certification of the applicant's on-the-job experience in phlebotomy, if applicable, including:

(A) Name and address of laboratory where employed, dates of employment, number of hours of experience in techniques specified in Section 1035.1 (f) and an estimate of the number of skin punctures, venipunctures or arterial punctures performed pursuant to the Business and Professions Code Section 1220 (d)(1) or (d)(2)(A) that fulfills all the sampling requirements of all clinical laboratory tests or examinations; and

(B) Signed documentation from the director of the laboratory that the above information accurately represents the applicant's experience in phlebotomy; and

(9) Evidence of satisfactory performance on a certification examination in phlebotomy administered by a certifying organization that was approved by the department pursuant to Section 1031.7 at the time the examination was administered; and

(10) Signature of the applicant, telephone number and date of application; and

(11) Payment of a two-year certification fee of \$50.

~~(e)~~(d) Timeframes for processing applications for licensure to direct a clinical laboratory or to perform clinical laboratory tests or examinations or for certification to perform phlebotomy pursuant to ~~e~~Chapter 3 of the Business and Professions Code shall be as follows:

(1) The department shall notify the applicant in writing, within 90 days of receipt of an application, of one of the following:

(A) The application is complete and will be processed by the department; or

(B) The application is incomplete and not accepted for processing. The department's written notification shall include the specific information, documentation or fee in which the application is deficient; or

(C) The application has been reviewed and does not meet the requirements and that approval is denied. The department shall give written notification of the basis for the denial.

(2) The department shall notify the applicant within 90 days of postmark date of resubmission of application requirements pursuant to ~~(e)(1)(B)~~ Section 1031.4 (d)(1)(B) whether the application has been approved or denied.

(3) Written notification by the department to applicants shall be deemed to occur on the date of the postmark from the department.

(4) The department shall deem an application abandoned by an applicant who fails to respond or to supply all information, documents, verifications or payment of applicable fees within 30 days of notification by the department.

(5) The department's time periods for processing an application for licensure or certification from the date the application is complete to the date the final decision is made regarding an approval are as follows:

- (A) The median time for processing an application is 90 days;
- (B) The minimum time for processing an application is 30 days; and
- (C) The maximum time for processing an application is 150 days.
- (e) Certification shall be valid for a period of 2 years unless revoked.
- (f) Failure to meet the requirements of this section shall be good cause for denial or revocation of approval by the department.
- (g) All applicants, licensees and certificants pursuant to Section 1031.4 shall notify the department in writing of any change(s) of name and /or address within 30 days after the change(s) has occurred.

NOTE: Authority cited: Section 1224, Business and Professions Code; Section 100275, Health and Safety Code; and Section 17520, Family Code.
Reference: Sections 1203, 1204, 1205, 1207, 1209, 1209.1, 1210, 1220, 1241, 1242, 1242.5, 1246, 1260, 1261, 1261.5, 1263, 1264, 1282, 1300, 1301, 1301.1, and 1320, Business and Professions Code; and Section 120580, Health and Safety Code.

(13) Amend Section 1031.5 to read:

1031.5. Requirements and Timeframes for Renewal of Licenses and
Certificates.

(a) In order to maintain a license in active status, licenses shall be renewed by filing a renewal application within 60 days prior to the end of the license period.

(b) A complete license renewal application shall include name and address of the licensee, license number, current work location(s), documentation of continuing education credits, an attestation stating whether ~~that~~ the licensee has or has not been convicted of any felonies or misdemeanors other than minor traffic violations in the previous two years year, license renewal fee, signature and date of application for renewal.

(c) In order to maintain a phlebotomy certificate in active status, certificates once approved shall be renewed at biennial intervals by filing a renewal application within 60 days prior to the end of the certificate period.

(d) A complete phlebotomy certificate renewal application shall include name and address of the certificant, certificate number, current work location(s), documentation of continuing education performed during the previous 24 months, an attestation stating whether the certificant has or has not been convicted of any felonies or misdemeanors other than minor traffic violations in the previous two years, certification renewal fee of \$50, signature and date of application for renewal.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code;
Reference: Sections 1203, 1204, 1205, 1207, 1209, 1209.1, 1210, 1226, 1241, 1242, 1242.5, 1246, 1260, 1261, 1261.5, 1263, 1264, 1282, 1300, 1301 and 1301.1, Business and Professions Code; and Section 120580, Health and Safety Code.

(14) Adopt a new Section 1031.7 to read:

1031.7. Conditions for Approval of Certifying Organizations to Administer
Phlebotomy Certification Examinations.

(a) In order for a certifying organization to be eligible for approval by the
department to administer a phlebotomy certification examination for state
certification purposes, the certifying organization shall meet the following
conditions:

(1) The certifying organization shall be a national, independent, not-for-profit,
professional certifying organization; and

(2) The certifying organization shall offer examinations in phlebotomy; and

(3) The certifying organization shall provide the following to the
department:

(A) The organization's name and address; and

(B) Names of the organization's officers and board of directors; and

(C) A description of the organization's structure;

and

(D) The identity of the person designated by the organization to be responsible
for overseeing the administration and coordination of all examination activities;

and

(E) A schedule of dates and times that the examination will be conducted within
the state; and

(F) Listing of procedures for monitoring the content, quality, validity and
relevance of the phlebotomy examinations pursuant to Section 1031.7 (b); and

(G) The philosophy of the organization, demonstrating a commitment to

accurate assessment of a candidate's preparation for phlebotomy certification.

(b) In order for a certifying organization's examination to be approved for certification purposes, the organization shall document the following standards to support a request for approval:

(1) Evaluation of relevant standards in phlebotomy and how the organization's examinations address knowledge and skills that would assure competence of the candidate; and

(2) Explanation of how the examinations are developed by the organization, using subject matter experts of clinical laboratory personnel; and

(3) Documentation that the organization's examinations are subject to annual review for current relevance; and

(4) Demonstration of the ability of the organization to evaluate their examinations, subjecting them to validity and reliability assessments using psychometric performance standards, and the capability of the organization to provide this information at least once yearly or upon request to the department.

(c) An organization approved to administer a phlebotomy examination shall:

(1) Agree to make the content of its examinations available to the department for confidential review; and

(2) Demonstrate how it will maintain security during administration of the examination, ensure the identity of the examinee, and maintain the confidentiality of the examination; and

(3) Document how it will make its records accessible to the department regarding those persons participating in the examination and their scores; and

(4) Provide verification of those persons successfully passing the

certification examination to the department and shall maintain these records for five years; and

(5) Issue a certificate to those passing the examination with the examinee's name, name of the certifying organization, type of certificate, effective date and official signature.

(d) Timeframes for processing applications for approval of a certifying organization's certification examination shall be as follows:

(1) Within 90 calendar days of receipt of an application, the department shall inform the organization in writing that the application is either complete and accepted for review or that it is deficient and what specific information or documentation is required to complete the application.

(2) Within 180 calendar days from the date of filing a completed application, the department shall inform the applicant certifying organization in writing whether the organization has been approved or denied as a certifying organization for the administration of the certification examination.

(3) The department shall deem an application abandoned by an applicant certifying organization that fails to respond or to supply all information, documents, or verifications within 30 days of notification pursuant to Section 1031.7(d)(1).

(4) The department's time periods for processing an application for approval as a certifying organization, from the receipt of the initial application to the final decision regarding the approval, is as follows:

(A) The median time for processing is 180 calendar days.

(B) The minimum time for processing is 90 calendar days.

(C) The maximum time for processing is 360 calendar days.

(e) Approval shall be valid for a period of four years unless revoked.

(f) To apply for renewal, a certifying organization shall file a renewal application at least 120 days prior to the end of the approval period providing the following:

(1) The name and address of the certifying organization; and

(2) Names of the organization's officers and board of directors; and

(3) Name of the person designated by the organization to be responsible for overseeing the administration and coordination of all examination activities; and

(4) A schedule of dates and times that the examination will be conducted within the state for the next 12 months; and

(5) A copy of the current examination; and

(6) Signature of the program director and date of application for renewal.

(g) Failure to meet the requirements of this section shall be good cause for denial or revocation of approval by the department.

(h) A certifying organization shall notify the department in writing of any change(s) pursuant to Subsections (a) through (c) within 30 days after the change(s) has occurred.

NOTE: Authority cited: Section 1224, 1320 Business and Professions Code; and Section 100275, Health and Safety Code.
Reference: Sections 1242, 1242.5, 1246 and 1269 Business and Professions Code; and Section 120580, Health and Safety Code.

(15) Repeal Section 1034:

~~1034. Unlicensed Personnel, Venipuncture and Skin Puncture and Arterial Puncture.~~

~~Pursuant to Section 1242.5 and Section 1246(b) of the Business and Professions Code, unlicensed persons may perform venipuncture, skin puncture or arterial puncture upon meeting the following training requirements:~~

~~(a) An unlicensed person employed by a licensed clinical laboratory may perform venipuncture and skin puncture for the purpose of withdrawing blood for test purposes upon specific authorization from a licensed physician and surgeon, provided he has been trained in the proper procedure to be employed in the performance of venipuncture and skin puncture. Ten clock hours of such training shall be the minimum acceptable, shall be carried out under the general supervision of a licensed physician and surgeon or clinical laboratory bioanalyst and the personal and direct supervision of one of these, and shall include instruction and demonstration regarding (1) pertinent anatomy and physiology; (2) choice of equipment; (3) proper technique; (4) care of specimen; (5) hazards and complications; and (6) postpuncture patient care, as well as performance by the unlicensed person of at least three venipunctures and three skin punctures. However, the licensed physician and surgeon or clinical laboratory bioanalyst in charge of such training may require more than this ten-hour minimum before certifying satisfactory completion by said unlicensed person. Upon satisfactory completion of the above training in venipuncture and skin puncture techniques, the physician and surgeon or clinical laboratory bioanalyst in charge of such~~

~~training shall prepare and issue to the unlicensed person a signed certificate stating that the named individual satisfactorily completed training which began and terminated on specified dates.~~

~~(b) An unlicensed person employed as a technician in respiratory services or cardiopulmonary laboratories in licensed clinics or hospitals may perform venipuncture and skin puncture in such services or laboratories for the purposes of withdrawing blood for test purposes if the training requirements outlines in subsection (a) of this section are fulfilled.~~

~~(c) An unlicensed person employed as a technician in respiratory services or cardiopulmonary laboratories in licensed clinics or hospitals may perform arterial puncture in such services or laboratories for the purposes of withdrawing blood for test purposes provided he has been trained in the proper procedure to be employed in the performance of arterial puncture. Ten clock hours of such training shall be the minimum acceptable, shall be carried out under the personal and direct supervision of the physician and surgeon director of said respiratory services or cardiopulmonary laboratories, or his medical associate and shall include instruction and demonstration regarding (1) pertinent anatomy and physiology; (2) choice of equipment; (3) proper technique; (4) care of specimen; (5) hazards and complications; (6) postpuncture patient care, as well as performance by the technician of at least three radial and three brachial arterial punctures. However, the physician and surgeon director, or his medical associate, in charge of such training may require more than this ten hour minimum before certifying satisfactory completion by said unlicensed person.~~

~~Upon satisfactory completion of the above training in arterial puncture technique the physician and surgeon in charge of such training shall prepare and issue to the technician a signed certificate stating that the named individual satisfactorily completed training which began and terminated on specific dates.~~

~~(d) Copies of certificates issued under this section shall be maintained in the respective training facilities for a period of at least two years.~~

NOTE: Authority cited: Sections ~~102 and 208~~ 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Section 1224 of the Business and Professions Code; and Section 100275, Health and Safety Code.

(16) Adopt new Section 1034 to read:

Section 1034. Certification of Phlebotomy Technicians.

(a) The education, training and experience required for certification in phlebotomy shall be as follows:

(1) For a person to be eligible for certification as a Limited Phlebotomy Technician, he or she shall:

(A) Be a high school graduate or achieved a passing score on the general educational development (GED) test or documentation of equivalent education pursuant to Section 1031.4(c)(6)(B); and

(B) Have completed a minimum of 20 hours basic didactic instruction pursuant to Section 1035.1(e)(1) from a phlebotomy training program approved by the department; and

(C) Have completed a minimum of 25 skin punctures, performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations, in a clinical setting on patients, under the supervision of a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, or licensed clinical laboratory scientist, who will certify in writing with a signed certificate that this training has been completed; and

(D) Apply to the department for certification as a Limited Phlebotomy Technician pursuant to Section 1031.4(c).

(2) For a person with no on-the-job experience in phlebotomy to be eligible for certification as a Certified Phlebotomy Technician I, he or she shall:

(A) Be a high school graduate, or achieved a passing score on the general educational development (GED) test or documentation of equivalent education pursuant to Section 1031.4(c)(6)(B); and

(B) Have completed a minimum of 40 hours didactic instruction pursuant to Section 1035.1(e) from a phlebotomy training program approved by the department; and

(C) Have completed a minimum of 40 hours practical instruction from a phlebotomy training program approved by the department pursuant to Section 1035.1(f), which instruction shall include completion of a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations; and

(D) Have passed a written examination in phlebotomy administered by a certifying organization approved by the department pursuant to Section 1031.7; and

(E) Apply to the department for certification as a Certified Phlebotomy Technician I pursuant to Section 1031.4(c).

(3) For a person who has less than 1040 hours on-the-job experience in phlebotomy to be eligible for certification as a Certified Phlebotomy Technician I, he or she shall:

(A) Be a high school graduate or achieved a passing score on the general educational development (GED) test or documentation of equivalent education pursuant to Section 1031.4(c)(6)(B); and

(B) Have completed a minimum of 40 hours didactic instruction pursuant to Section 1035.1(e) from a phlebotomy training program approved by the department; and

(C) Have a letter signed by a licensed physician and surgeon or licensed clinical laboratory bioanalyst directing the laboratory employing the person attesting his or her completion of a specified number of hours of on-the-job experience in phlebotomy within the previous five years, which shall include the activities listed in Section 1035.1(f) and completion of a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations; and

(D) Have passed a written examination in phlebotomy administered by a certifying organization approved by the department, as specified in Section 1031.7; and

(E) Apply to the department for certification as a Certified Phlebotomy Technician I pursuant to Section 1031.4 (c).

(4) For a person who has 1040 hours or more of on-the-job experience in phlebotomy to be eligible for certification as a Certified Phlebotomy Technician I, he or she shall:

(A) Be a high school graduate or achieved a passing score on the general educational development (GED) test or documentation of equivalent education pursuant to Section 1031.4(c)(6)(B); and

(B) Have completed a minimum of 20 hours advanced didactic instruction pursuant to Section 1035.1(e)(2) from a phlebotomy training program approved by the department; and

(C) Have a letter signed by a licensed physician and surgeon or licensed clinical laboratory bioanalyst directing the laboratory employing the person attesting his or her completion of a specified number of hours of on-the-job experience in phlebotomy within the previous five years which shall include the activities listed in Section 1035.1(f) and completion of a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations; and

(D) Have passed a written examination in phlebotomy administered by a certifying organization approved by the department pursuant to Section 1031.7; and

(E) Apply to the department for certification as a Certified Phlebotomy Technician I pursuant to Section 1031.4(c).

(5) For a person to be eligible for certification as a Certified Phlebotomy Technician II, he or she shall:

(A) Be a Certified Phlebotomy Technician I who holds a current, valid certificate from the department or who meets certification requirements as a Certified Phlebotomy Technician I pursuant to Section 1034(a)(4)(A) – (D) and who has at least 1040 hours on-the-job experience in phlebotomy in the previous 5 years as

certified in writing by the director(s) of the laboratory(ies) employing the person;
and

(B) Have completed a minimum of 20 arterial punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations and performed under the general overall responsibility of a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, respiratory care practitioner or a licensed clinical laboratory scientist, who will certify in writing that this person has completed this practical instruction; and

(C) Apply to the department for certification as a Certified Phlebotomy Technician II pursuant to Section 1031.4(c).

(b) Performance of phlebotomy by a person certified by the department shall be limited as follows:

(1) A Limited Phlebotomy Technician shall perform skin punctures only when he or she:

(A) Maintains a current, valid certification with the department as a Limited Phlebotomy Technician; and

(B) Performs skin punctures under the supervision of a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, licensed clinical laboratory scientist or a designee. A designee shall be licensed or certified under Chapter 3 of the Business and Professions Code and shall be accountable to the laboratory director for skin punctures and other duties related to blood collection performed by the Limited Phlebotomy Technician. The supervisor shall review the work of the technician at least once

a month and be accessible to the location where the technician is working to provide on-site, telephone, or electronic consultation when blood is being collected; and

(C) Is shown to be competent to perform skin punctures after employment without direct and constant supervision before being allowed to perform skin puncture on patients. Documentation of competency shall be done at least annually; and

(D) Has completed at least three hours per year, or six hours every two years, of continuing education in phlebotomy related courses from a provider of continuing education approved pursuant to Article 2.5; and

(E) Has posted at the work location in the laboratory employing the person, a current, valid state certificate as a Limited Phlebotomy Technician. When performing skin punctures away from the posted location, the Limited Phlebotomy Technician shall carry a current, valid identification card issued by the department attesting the person's name, certificate type and effective dates of certification as a Limited Phlebotomy Technician.

(2) A Certified Phlebotomy Technician I shall perform skin punctures and venipunctures only when he or she:

(A) Maintains a current, valid certification with the department as a Certified Phlebotomy Technician I; and

(B) Performs skin punctures and venipunctures under the supervision of a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, licensed clinical laboratory scientist or a designee. A designee shall be a person licensed or certified under Chapter 3 of the Business and Professions Code and shall be accountable to the laboratory

director for skin punctures, venipunctures and other duties related to blood

collection performed by the Certified Phlebotomy Technician I. The supervisor shall review the work of the technician at least once a month and be accessible to the location where the technician is working to provide on-site, telephone, or electronic consultation as needed; and

(C) Is shown to be competent to perform skin puncture and venipuncture after employment without direct and constant supervision before being allowed to perform skin punctures or venipunctures on patients. Documentation of competency shall be done at least annually; and

(D) Has completed at least three hours per year, or six hours every two years, of continuing education in phlebotomy related courses from a provider of continuing education approved pursuant to Article 2.5; and

(E) Has posted at the work location of the laboratory employing the person, a current, valid state certificate as a Certified Phlebotomy Technician I. When performing skin punctures or venipunctures away from the posted location, the Certified Phlebotomy Technician I shall carry a current, valid identification card issued by the department attesting the person's name, certificate type and effective dates of certification as a Certified Phlebotomy Technician I.

(3) A Certified Phlebotomy Technician II shall perform skin punctures and venipunctures only under conditions pursuant to Section 1034(b)(2), and shall be limited to performing arterial punctures only when a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, licensed clinical laboratory scientist or a respiratory care practitioner is present at the location during performance of an arterial puncture, and when he or she:

(A) Maintains a current, valid certification with the department as a Certified

Phlebotomy Technician II; and

(B) Is shown to be competent to perform arterial punctures after employment by direct, personal observation and documentation of his or her expertise in arterial punctures by a licensed physician and surgeon, licensed physician assistant, licensed clinical laboratory bioanalyst, registered nurse, licensed clinical laboratory scientist or a respiratory care practitioner. Documentation of competency shall be done at least annually; and

(C) Has completed at least three hours per year, or six hours every two years, of continuing education in phlebotomy related courses from a provider of continuing education approved pursuant to Article 2.5; and

(D) Has posted at the work location in the laboratory employing the person, a current, valid state certificate as a Certified Phlebotomy Technician II. When performing arterial punctures, skin punctures, or venipunctures away from the posted location, the Certified Phlebotomy Technician II shall carry a current, valid identification card issued by the department attesting the person's name, certificate type and effective dates of certification as a Certified Phlebotomy Technician II.

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1206, 1208, 1212, 1220, 1242, 1242.5, 1246 and 1269, Business and Professions Code; and Section 120580, Health and Safety Code.

(17) Repeal Section 1034.1:

~~1034.1 Unlicensed Personnel, Laboratory Aides.~~

~~Pursuant to Section 1269 of the Business and Professions Code, a laboratory aide who is a high school graduate, or has equivalent education as determined by the department, is authorized to assist licensed personnel, other than trainees, in a licensed clinical laboratory if he works under the direct and constant supervision of a licensed person, other than a trainee, and has demonstrated satisfactorily to the director of the laboratory in which employed ability to engage in activities such as: labeling, centrifuging and transferring specimens, transcribing results which have been previously recorded either manually or mechanically, preparing equipment, culture media, and reagents, and provided that the following conditions exist:~~

~~(a) When manual methods are employed in the performance of clinical laboratory tests licensed personnel, other than trainees, must perform any test or part thereof which involves the quantitative measurement of the specimen or test reagent, or any mathematical calculation relative to determining the results or the validity of a test procedure, except that;~~

~~(1) in the case of qualitative and semi-quantitative "spot, tablet, or stick" tests, the aide may add the test reagent to the specimen or vice versa, as the case may be, but the results must be checked by the licensed person.~~

~~(2) in the case of microbiological tests to aide may make primary inoculations of test material to be cultured onto appropriate media and stain slide preparations for microscopic examination.~~

~~(b) when mechanical and electronic instruments are used in the performance of clinical laboratory tests licensed personnel, other than trainees, must:~~

- ~~(1) Initially standardize or calibrate the instrument and periodically check its performance by monitoring results of appropriate standards and controls.~~
- ~~(2) Read and record test results unless this is done mechanically by the instrument in the form of a digital read-out or a recording mechanism onto pre-calibrated charts.~~
- ~~(3) quantitatively measure all samples and reagents unless done automatically by the instrument in the course of its normal operation or by the use of previously calibrated and approved automatic syringes or other dispensers.~~

NOTE: Authority cited: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.
Reference: Section 1224, Business and Professions Code; and Section 100275, Health and Safety Code.

(18) Adopt new Section 1035.1 to read:

Section 1035.1. Phlebotomy Training Program Requirements.

(a) In order to be eligible for approval by the department to provide didactic and/or practical phlebotomy instruction leading to certification of phlebotomists, a phlebotomy training program shall meet the requirements of this section and be offered by either a:

(1) National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) approved program for training phlebotomists; or

(2) Accredited college or university; or

(3) Private, post-secondary program or occupational program registered or approved by the Bureau for Private Postsecondary and Vocational Education; or

(4) California Adult Education or Regional Occupational Program (ROP); or

(5) United States of America military medical laboratory specialist program; or

(6) California licensed clinical laboratory.

(b) A phlebotomy training program shall be directed by a licensed physician and surgeon, licensed physician assistant, registered nurse, or person licensed under Chapter 3, who shall be responsible for:

(1) Overall operation and administration of the phlebotomy training program; and

(2) Ensuring the quality of the technical, scientific and clinical instruction; and

(3) Ensuring that the person(s) providing instruction meets the qualifications of this section; and

(4) Ensuring that the person(s) providing instruction is competent and that his or her work performance is periodically evaluated, monitored and documented.

(c) The person(s) providing instruction shall be a :

(1) Licensed physician and surgeon; or

(2) Licensed physician assistant; or

(3) Registered nurse; or

(4) Person licensed under Chapter 3; or

(5) Respiratory care practitioner with a minimum of 2 years experience in the previous 5 years; or

(6) Certified phlebotomy technician with a minimum of 3 years of experience in the previous 5 years or a phlebotomist with 3 years of experience in the previous 5 years and employed as a phlebotomy instructor, who shall meet certification requirements pursuant to Section 1034(a)(4) on or before December 31, 2003.

(d) Person(s) specified in Subsection (c)(1) through (5) shall pass a written examination in phlebotomy, administered by a certifying organization approved by the department pursuant to Section 1031.7 either:

(1) Prior to employment by a phlebotomy training program approved by the department pursuant to this section; or

(2) No later than December 31, 2003, if employed as a phlebotomy instructor on or before December 31, 2002.

(e) An approved phlebotomy training program shall provide the following didactic instruction to its students:

(1) A basic phlebotomy curriculum consisting of a minimum of 20 hours lecture and testing for knowledge of:

(A) Basic infection control, universal precautions and safety; and

(B) Basic anatomy and physiology of body systems with emphasis on the circulatory system, the appropriate medical terminology; and

(C) Proper identification of patient and specimens, the importance of accuracy in overall patient care; and

(D) Proper selection and preparation of skin puncture site, including selection of antiseptic; and

(E) Blood collection equipment, types of tubes and additives, proper order of draw when additives are required, special precautions; and

(F) Post-puncture care; and

(G) Appropriate disposal of sharps, needles and waste.

(2) An advanced phlebotomy curriculum consisting of a minimum of 20 hours of lecture and testing for knowledge of:

(A) Advanced infectious disease control and biohazards; and

(B) Anti-coagulation theory; and

(C) Knowledge of pre-analytical sources of error in specimen collection, transport, processing and storage; and

(D) Anatomical site selection and patient preparation; and

(E) Risk factors and appropriate responses to complications which may arise from phlebotomy; and

(F) Recognition of, and corrective actions to take, with problems in test requisitions, specimen transport and processing; and

(G) Applications of basic concepts of communication, interpersonal relations, stress management, professional behavior, ethics and legal implications of phlebotomy; and

(H) Quality assurance in phlebotomy necessary to provide accurate and reliable laboratory test results; and

(I) Legal issues related to blood collection.

(f) An approved phlebotomy training program shall provide a clinical setting for a minimum of 40 hours of practical instruction in phlebotomy. This setting shall provide access to patients whose blood is being tested by a clinical laboratory. In order for a program to be eligible for approval by the department, it shall provide documentation of a training curriculum that includes:

(1) Selection of blood collection equipment appropriate to test requisitions; and

(2) Preparation of the patient and infection control; and

(3) Skin punctures for testing purposes from patients of varying ages, including pediatric and geriatric, and of varying health and obesity status; and

(4) Venipunctures from patients of varying ages, health and obesity status; and

(5) Post-puncture care; and

(6) Processing of blood containers after collection, including centrifugation; and

(7) Proper disposal of needles, sharps and medical waste; and

(8) Observation of arterial punctures; and

(9) A practical examination showing evidence of successful completion of Subsections (f)(1) through (7).

(g) A phlebotomy training program shall be responsible for assuring that a student completes a minimum of 10 skin punctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements and 50 venipunctures performed pursuant to the Business and Professions Code Section 1220(d)(1) or (d)(2)(A) that fulfill all sampling requirements of all clinical laboratory tests or examinations during or after his or her practical instruction.

(h) A phlebotomy training program shall provide a certificate of completion to its students upon satisfactory completion of the program. The program shall

maintain a copy of this certificate for five years. This certificate shall be signed by the director of the program and shall include:

(1) Name and address of the training program; and

(2) Name of the student; and

(3) Statement of satisfactory completion of the program; and

(4) Dates that training began and ended.

(i) A phlebotomy training program seeking approval from the department shall provide documentation to substantiate that its program objectives meet training criteria stated in this section. Verification may include an on-site inspection of the program.

(j) A complete application for phlebotomy training program approval shall include the following:

(1) Name and address of the training program; and

(2) Location(s) of all sites where didactic and practical instruction occur; and

(3) Name(s) and license number(s) of the physician and surgeon, physician assistant, registered nurse, or person licensed under Chapter 3 who is directing the program; and

(4) Name(s), license number(s) or certificate number(s), experience in phlebotomy, and evidence of satisfactory performance on a phlebotomy certification examination administered by a certifying organization with departmental approval in effect at the time the examination was administered, of every physician and surgeon, physician assistant, registered nurse, person licensed under Chapter 3, respiratory care practitioner, certified phlebotomy technician, or phlebotomist pursuant to Subsection (c)(6) who is supervising or providing instruction; and

(5) List of equipment, supplies and educational materials used for instruction; and

(6) Curriculum and instructional objectives, including hours spent at each activity.

(k) Timeframes for approval of training programs shall be as follows:

(1) Submission of an application for approval shall be deemed to occur on the date the complete application is received by the department.

(2) Written notification by the department to the applicant shall be considered to occur on the date the documents are postmarked.

(3) The department shall notify the applicant within 60 days of submission of an application for training program approval, of one of the following:

(A) That the application is complete and acceptable for processing by the department; or

(B) That the application is incomplete and not accepted for processing. This notification shall include the specific information or documentation that the applicant shall submit within 30 days in order for the department to consider the application acceptable; or

(C) That the application has been reviewed and does not meet the requirements of this section and that approval is denied.

(4) The department shall consider an application to have been abandoned by any applicant who fails to respond to the department's request to submit specific information or documentation within 30 days of notification pursuant to Section 1035.1(k)(3)(B).

(5) The department's time periods for processing an application, from the date the initial application is received to the date the final decision is made regarding approval, are as follows:

- (A) The median time for processing an application is 90 days.
- (B) The minimum time for processing is 30 days.
- (C) The maximum time for processing is 150 days.
- (l) Approval shall be valid for a two-year period.
- (m) To apply for renewal, a training program shall file a renewal application at least 60 days prior to the end of the approval period and provide the following:
- (1) The name and address of the training program; and
 - (2) The name and license number of all directors; and
 - (3) The name, license or certificate number of all instructors; and
 - (4) The name(s) and location(s) of all didactic and practical instruction; and
 - (5) The curriculum and instructional objectives, including hours spent at each activity; and
 - (6) The schedule of didactic and practical instruction for the next 24 months; and
 - (7) The listing of students who completed its program and the total number of students who enrolled in its program in the previous approval period; and
 - (8) The signature of the director(s) and date of the application for renewal.
- (n) Failure to meet the requirements of this section shall be good cause for denial or revocation of approval by the department.
- (o) The training program shall notify the department in writing of any change(s) pursuant to Subsections (a) through (h) within 30 days after the change(s) has occurred.

NOTE: Authority cited: Section 1224, 1320 Business and Professions Code; and Section 100275, Health and Safety Code.

Reference: Sections 1208, 1220, 1222, 1222.5, 1242, 1242.5, 1246, 1269, and 1300, Business and Professions Code; and Section 120580, Health and Safety Code.